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Appln. No. 10/011,011 Docket No. 14XZ00088/GEM-0202

# REMARKS / ARGUMENTS

## Status of Claims

Claims 2-55, 57, 59 and 60 are pending in the application. Claims 2-55, 57, 59 and 60 stand rejected.

Applicant has amended claims 57, 59, and 60, leaving claims 2-55, 57, 59 and 60 for consideration upon entry of the present Amendment.

Applicant respectfully submits that the rejections under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §102(b) have been traversed, that no new matter has been entered, and that the application is in condition for allowance.

#### No New Subject Matter

Applicant respectfully submits that no new subject matter has been introduced through the amendments to claims 57, 59, and 60. For example, clear support and antecedent basis for the attached amendments may be found in, at least, the subject application as originally filed in paragraphs [0024-0027], [0031], and [0037].

As requested by the Examiner (see Office Action, page 3, section IV), the attached amendments include terminology directly supported by the cited portions of the specification to aid in expediting prosecution.

For example, as set forth in paragraph [0024-0027], "[f]igures 1 and 2 illustrate, in general, the stages of operation on a stenosis by means of an endovascular prosthesis," "the endovascular prosthesis 2 is a deployable cylinder," and "the method according to the invention provides for simulation of the stages described above" (emphasis added). Furthermore, as set forth in paragraph [0037], "it is also possible in the course of an operation ... to execute the method and to visualize the simulated final state of the operation" (emphasis added). More clearly, the specification sets forth the actual operation on a stenosis and the simulation of the actual operation, including simulation of the endovascular prosthesis which is a deployable or real prosthesis.

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Therefore, Applicants submit that all the attached amendments have full support in the specification as originally filed, as shown in the examples given above in addition to other portions of the specification.

# Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 2-55, 57 and 59-60 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Applicant respectfully traverses this rejection.

The Examiner argues that the claims lack clarity regarding the terms "endovascular prosthesis," "prosthesis," and "interventionally deployed prosthesis." More particularly, the Examiner states that the claims are not clear as to which "prosthesis" is being referred to.

Applicant submits that as presently amended, the claims more clearly recite distinct prostheses. Furthermore, Applicant has amended the claims to more clearly refer to each of the distinct prostheses. Therefore, Applicant believes the Examiner's rejection to be traversed through the attached amendments, as antecedent basis for the terms within the claims is conveyed more clearly.

Furthermore, it should be understood that these amendments have not been entered to overcome the prior art, as they are in direct response to the Examiner's argument for lack of clarity. Therefore, no presumption should attach that either the claims have been narrowed over that earlier presented, or that subject matter or equivalents thereof to which the Applicant is entitled have been surrendered.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw this rejection, which Applicant considers to be traversed.

# Rejections Under 35 U.S.C. §102(b)

Claims 2-55, 57 and 59-60 stand rejected under 35 U.S.C. §102(b) as being anticipated by Haridas et al, Medical Device and Diagnostic Industry Magazine

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"Predictive Analysis at the Forefront of Medical Product Development", hereinafter Haridas. Applicant respectfully traverses this rejection.

Applicant respectfully submits that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Moreover, "[t]he identical intention must be change in community describe in a rout ine identified technemy "arranged as in the claim." Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. Titanium Metals Corp. v. Banner, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).

Applicant has amended independent claims 59, and 60 to now recite, inter alia, "in the course of an actual interventional operation ... deploying via simulation a simulated endovascular prosthesis into the blood vessel ... interventionally deploying the endovascular prosthesis in the blood vessel at the lesion during the actual interventional operation" (emphasis added). Independent claim 57 has been amended to recite somewhat similar features to those noted above, although it should be interpreted solely by those features recited therein. Dependent claims inherit all of the limitations of the respective parent claim.

In alleging anticipation, the Examiner asserts that Haridas discloses the content of the independent claims at Page 4, "What if' Material Sensitivity Studies; Page 5, Paragraph 1; Page 6, Paragraphs 1-2; and Figures 7-8 [paper 20060928, page 16].

Applicant respectfully disagrees for the following reasons. Haridas discloses "...Such material data allow the simulation of the device tissue interaction problem to be exercised over the entire range of statistical variability, allowing the function of the device and the materials to be fully assessed." [Haridas, Page 4, "What if" Material

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Sensitivity Studies]. Haridas also discloses "...Additional tests to characterize the response of the polymer under constrained conditions, such as biaxial stretching, must be performed to generate the appropriate material constants for input into the finite element calculations." [Haridas, Page 5, paragraph 1]. Haridas further discloses, "...finite element modeling of the balloon positioned within the lumen of the stenosis and then inflated against a virtual blocked vessel (Figures 8-10)." [Haridas, Page 6, paragraph 1].

Thus, Haridas discloses a <u>modeling</u> method that involves a methodology absent of real time steps or any actual interventional operation.

Therefore, in contrast to the claimed invention, Applicant respectfully submits that Haridas is absent disclosure of both a "simulated endovascular prosthesis" and an "endovascular prosthesis" deployed in an actual interventional operation as set forth in independent claims 57, 59, and 60: in the course of an actual interventional operation ... deploying via simulation a simulated endovascular prosthesis into the blood vessel ... interventionally deploying the endovascular prosthesis in the blood vessel at the lesion during the actual interventional operation" (emphasis added).

Accordingly, Applicant submits that Haridas does not disclose all of the claimed elements arranged as in the claim, and absent anticipatory disclosure in Haridas of each and every element of the claimed invention arranged as in the claim, Haridas cannot be anticipatory.

In view of the amendments and foregoing remarks, Applicant submits that Haridas does not disclose each and every element of the claimed invention arranged as claimed and therefore cannot be anticipatory. Accordingly, Applicant respectfully submits that the Examiner's rejection under 35 U.S.C. §102(b) has been traversed, and requests that the Examiner reconsider and withdraw of this rejection.

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## CONCLUSION

In light of the forgoing, Applicant respectfully submits that the Examiner's rejections under 35 U.S.C. §112, second paragraph, 35 U.S.C. §102(b), have been traversed, and respectfully requests that the Examiner reconsider and withdraw these rejections.

If a communication with Applicant's Attorneys would assist in advancing this case to allowance, the Examiner is respectfully requested to contact the undersigned so that any such issues may be promptly resolved.

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment, to Deposit Account No. 50-2513.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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